

Message

From: Herrick, Jacquelyn [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40DA8860B1DD43D9B006AC1E0E9E04CE-MARCHESE, J]
Sent: 1/25/2021 6:12:14 PM
To: Schaible, Stephen [Schaible.Stephen@epa.gov]
Subject: RE: Request a short call for clarification / PRIA?

Weird, I did send him the invite this morning. I'll make sure he received it.

Thanks,
Jackie

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0559
herrick.jacquelyn@epa.gov

From: Schaible, Stephen <Schaible.Stephen@epa.gov>
Sent: Monday, January 25, 2021 1:11 PM
To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: RE: Request a short call for clarification / PRIA?

Hi Jackie,

I don't see Kerry on the meeting attendee list. Are you and Marietta in good shape to present his input in science work needed and implications for PRIA category?

Steve

Stephen A. Schaible, PRIA Coordinator
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

From: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Sent: Monday, January 25, 2021 1:04 PM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>
Cc: Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Schaible, Stephen <Schaible.Stephen@epa.gov>; Leifer, Kerry <Leifer.Kerry@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Subject: RE: Request a short call for clarification / PRIA?

Sounds good. Thank you Marietta.

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs

U.S. Environmental Protection Agency
(703) 347-0559
herrick.jacquelyn@epa.gov

From: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Sent: Monday, January 25, 2021 11:44 AM
To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>
Cc: Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Schaible, Stephen <Schaible.Stephen@epa.gov>; Leifer, Kerry <Leifer.Kerry@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Subject: RE: Request a short call for clarification / PRIA?

Thanks Jackie! Looping in Mike and Ed for awareness. I will look to you to lead our responses for RD.

From: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Sent: Monday, January 25, 2021 11:34 AM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>
Cc: Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Schaible, Stephen <Schaible.Stephen@epa.gov>; Leifer, Kerry <Leifer.Kerry@epa.gov>
Subject: RE: Request a short call for clarification / PRIA?

Hi all,

Based on my discussion this morning with Steve and Kerry, I've updated the responses directly below in red. The answers that remain unchanged are still in green. This is just an FYI for you all before the meeting this afternoon. Let me know if you'd like me to reach out to anyone else before the call.

1. RD has previously, for other products and other packaging, required submission of an R340 amendment for a new packaging form. This new package is also HDPE is the same style ("F-style", jerican, and drum) and volume as current Clarke registrations. **Does the alternate barrier technology for an otherwise identically constructed HDPE container trigger the PRIA submission? Yes.**
2. If PRIA submission is required, what turn-around time from RD might Clarke expect for its submissions? The PRIA code would depend on what information is submitted and what information is found during EPA's review. If only physical chemical property data are submitted (PRIA code R340, 4 month review frame) RD chemists would conduct the original review. However, if PFAS is still determined to be present, the RD team would likely need to consult with HED triggering an R350 PRIA code (9 months).
3. Will it be possible to submit applications for multiple products of similar composition as part of an aggregate package for ease of review? **Ex. 5 Deliberative Process (DP)**
Ex. 5 Deliberative Process (DP)
4. Might fees be less for grouped applications of products that reference the same study (i.e., multiple formulations tested in a single study), i.e. R340 and R340.1 with a 25% fee reduction? **This would depend on how the products differ and how the information submitted for each product differs. This determination would likely happen after the application is submitted. The full fee will be needed up front, and the determination for a fee reduction could be made after submission.**
5. For a study that details stability and corrosion characteristics for multiple products, in CDX/PSP would we upload the study for one registration/action, or would we upload it repeatedly for every product application package? Does EPA have a preference? **Ex. 5 Deliberative Process (DP)**
Ex. 5 Deliberative Process (DP)
6. We are submitting data to support a basic registrant's submission for a Clarke branded product that is a supplemental distributor label. How might we connect the submissions for expediency? **Ex. 5 Deliberative Process (DP)**
Ex. 5 Deliberative Process (DP)

Thanks,
Jackie

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0559
herrick.jacquelyn@epa.gov

From: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Sent: Monday, January 25, 2021 7:35 AM
To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>
Cc: Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Schaible, Stephen <Schaible.Stephen@epa.gov>
Subject: RE: Request a short call for clarification / PRIA?

Thanks Jackie.

The meeting with Clarke is today at 1:30. I forwarded the invitation. Please talk to Steve Schaible before the meeting this afternoon to get some input on the PRIA questions. I don't think we want to wait until Thursday to provide feedback.
Thanks

From: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Sent: Friday, January 22, 2021 8:12 PM
To: Aubee, Catherine <Aubee.Catherine@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Cc: Saunders, Jennifer <Saunders.Jennifer@epa.gov>
Subject: RE: Request a short call for clarification / PRIA?

Hi all,

Some initial thoughts below in green.

Thanks,
Jackie

Jacquelyn Herrick, PM 3
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0559
herrick.jacquelyn@epa.gov

From: Aubee, Catherine <Aubee.Catherine@epa.gov>
Sent: Friday, January 22, 2021 3:13 PM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Cc: Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Subject: RE: Request a short call for clarification / PRIA?

Internal, enforcement and compliance

Thanks – looping in the team.

FYI. they have a new product application in house for a product very similar to Anvil. We gave OECA and OGC a heads up.

Best,
Catherine

From: Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Sent: Friday, January 22, 2021 3:07 PM
To: Aubee, Catherine <Aubee.Catherine@epa.gov>
Subject: FW: Request a short call for clarification / PRIA?

Heads up. This is coming your way...

From: Messina, Edward <Messina.Edward@epa.gov>
Sent: Friday, January 22, 2021 3:06 PM
To: Karen Larson <klarson@clarke.com>
Cc: Nesci, Kimberly <Nesci.Kimberly@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>
Subject: RE: Request a short call for clarification / PRIA?

Happy to chat. Mike can work with the team.

Ed

From: Karen Larson <klarson@clarke.com>
Sent: Friday, January 22, 2021 1:50 PM
To: Messina, Edward <Messina.Edward@epa.gov>
Subject: Request a short call for clarification / PRIA?

Hi Ed,

As I shared previously, Clarke has identified an alternate packaging option for its drums and small volume containers that does not employ a fluorination barrier technology. We are quickly wrapping up our initial testing, including storage stability & container compatibility testing. I am hopeful that the test results will confirm suitability and already have the team preparing administratively for the next steps.

Are you available for a short call concerning our next steps for implementation, or could you ask the team to review the first set of questions below? I'm sure there may be other questions as we prepare our submissions. As you know, Clarke will be making a package change for all of its liquid registered products (up to 30 in total).

1. RD has previously, for other products and other packaging, required submission of an R340 amendment for a new packaging form. This new package is also HDPE is the same style ("F-style", jerican, and drum) and volume as current Clarke registrations. **Does the alternate barrier technology for an otherwise identically constructed HDPE container trigger the PRIA submission?** ☐ Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

2. If PRIA submission is required, what turn-around time from RD might Clarke expect for its submissions? ☐

Ex. 5 Deliberative Process (DP)

3. Will it be possible to submit applications for multiple products of similar composition as part of an aggregate package for ease of review? ☐ Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

4. Might fees be less for grouped applications of products that reference the same study (i.e., multiple formulations tested in a single study), i.e. R340 and R340.1 with a 25% fee reduction? ☐ Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

5. For a study that details stability and corrosion characteristics for multiple products, in CDX/PSP would we upload the study for one registration/action, or would we upload it repeatedly for every product application package? Does EPA have a preference? The study can be uploaded once with one MRID number. Each application should include a revised data matrix which should reference the MRID number given to the study.
6. We are submitting data to support a basic registrant's submission for a Clarke branded product that is a supplemental distributor label. How might we connect the submissions for expediency? MGK should be the one submitting studies to support their "basic registration" not Clarke.

Thank you and best regards,

Karen Larson
Vice President
Product Innovation & Government Affairs



675 Sidwell Court
St. Charles, Illinois 60174
U.S.A.
Office: 630-671-3123
www.clarke.com